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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,126

03/17/2004

James Robert Schwartz

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EXAMINER

ARNOLD, ERNST V

ART UNIT

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MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,126	Applicant(s) SCHWARTZ ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8, 11, 12, 14, 15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 11, 12, 14, 15, and 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3, 8, 11, 12, 14, 15, and 17-28 are under examination. Claims 4-7, 9, 10, 13, and 16 have been cancelled.

Withdrawn rejections:

Applicant's Declaration, amendments and arguments filed 5/25/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8, 11, 12, 14, 15, and 17-28 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhat et al. (WO 96/25913) in view of Gavin et al. (WO 01/00151).

Applicant claims:

- 1) (currently amended) A composition comprising:
 - a) from about 0.01 weight% to about 5 weight%, based on the total weight of the composition, of pyrrithione or a polyvalent metal salt of a pyrrithione, wherein the pyrrithione or polyvalent metal salt of pyrrithione is zinc pyrrithione;
 - b) from about 0.001 weight% to about 10 weight%, based on the total weight of the composition, of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc-containing layered material comprises an impurity containing hydroxy-containing basic zinc carbonate and further wherein the ratio of zinc-containing layered material to said pyrrithione or a polyvalent metal salt of pyrrithione is from about 1:2 to about 3:1.

Determination of the scope and content of the prior art

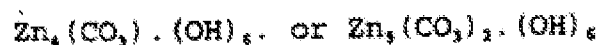
(MPEP 2141.01)

Bhat et al. teach compositions comprising monophasic zinc hydroxycarbonate as antimicrobial agent in **personal care products**, such as shampoos, wherein there is a *synergistic action* of **zinc hydroxycarbonate** with detergent and/or anti-**dandruff** actives like **zinc pyrrithione** in shampoos/hair dressings (pg. 8, lines 1-18 and claims 1-5 and 7). Thus, the art has already established compositions comprising zinc hydroxycarbonate and zinc pyrrithione in personal care products. Bhat et al. further

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teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of **0.1-20 wt.%** (Claims 1 and 2), wherein the structure of the zinc compound is $Zn_5(OH)_6(CO_3)_2 \cdot X H_2O$, where X varies between 0 and 4 (pg. 6, lines 23-27). When X=0 the same formula for **basic zinc carbonate**, a zinc-containing layered material, as disclosed by Applicants is taught (instant specification pg. 5, lines 16-20), which would intrinsically possess the same **augmentation factor greater than 1** as instantly claimed. From pages 1-2:

35 Basic zinc carbonate may be represented by



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and sometimes it is accompanied with ZnO.

The monophasic zinc hydroxycarbonate of the present invention has the following formula

5



Since Applicant claims the zinc hydroxy carbonate when X = 0 (see instant claim 8), then any additional water represents an impurity to the 'pure' composition. The Examiner notes that 'impurities' are not defined in the specification as filed and that in

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[0033] of the USPGPUB it only teaches that other impurities may be incorporated in the crystal lattice. Therefore, water is interpreted as an impurity. Bhat et al. a method of making a composition by adding zinc hydroxycarbonate to a mixture (pg. 12, lines 1-31).

Bhat et al. teach various methods of making the basic zinc carbonate such as on page 5-6 and claim 6:

25 The process of the present invention for the preparation of zinc hydroxycarbonate, (suitable for use as antimicrobial agent in personal care compositions such as soaps, cosmetic - skin and hair- and dental formulations) comprises

30 (i) dissolving a soluble zinc salt in water and heating it, to keep the solution warm before use,

(ii) dissolving an alkali metal carbonate, such as sodium potassium or ammonium carbonate, in water,

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(iii) taking water in a precipitation vessel and maintaining it at 35-95 °C,

(iv) pumping warm solutions of (i) and (ii) into the precipitation vessel simultaneously, and maintaining the temperature at 50-98 °C with continuous stirring and warming if necessary,

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(v) filtering off the precipitate and washing it with water until it is free from anions, and

(vi) drying the washed material.

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It is the Examiner's position that making this basic zinc carbonate intrinsically forms a layered film of an *in-situ* product reaction product because it is the same material as instantly claimed.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from **0.001 to 10% zinc pyrithione**; from **0.001 to about 10% of a zinc salt** and an anionic deterative surfactant for a topical carrier (Claim 1). Thus if 10% zinc salt is present and 1% zinc pyrithione then a ratio of 10:1 is obtained or 10% zinc salt and 3.3% zinc pyrithione for a ratio of about 3:1 or there can be 5% of zinc salt and 10% of zinc pyrithione for a ratio of about 1:2. Gavin et al. disclose aqueous antimicrobial shampoo compositions containing zinc salt and zinc pyrithione and claim a shampoo composition comprising mixtures of zinc carbonate, zinc oxide, zinc hydroxide, cuprous ammonium carbonate, etc... (See examples 3-13 page 57-58 and claim 6). **Methods pertaining to treating microbial infections** preferably related to **dandruff** and treating athlete's foot, a contagious **fungal infection** (Claim 9).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach the amount of zinc pyrithione present; the various 'augmentation factors'; or gallery ions in the zinc-containing layered material. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

2. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach a method for preparing a personal care composition by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound; wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

3. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach a method of treating microbial infections or fungal infections. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Bhat et al. with the amount of zinc pyrithione as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bhat et al. already teach adding zinc pyrithione and Gavin et al provide guidance as to how much to add. The 'augmentation factors' and presence of gallery ions are intrinsic to the composition since the same materials are used by Applicant.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Bhat et al. with the amount of

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zinc pyrithione as suggested by Gavin et al. by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound; wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is merely judicious selection of steps to combine the ingredients by one of ordinary skill in the art. With regard to the amount of carbonate or bicarbonate to add to make the instantly claimed ratios, it is the Examiner's position that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Bhat et al. already teach how to make the basic zinc carbonate and it is merely a design choice to make it *in situ*; step wise or simultaneously in the absence of evidence to the contrary.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition of Bhat et al. in a method of treating

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microbial infections or fungal infections as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest these uses for the composition.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant has amended the claims to be directed to an impurity containing hydroxy-containing basic zinc carbonate and has argued that Bhat teaches a pure basic zinc carbonate without impurity. Applicant asserts that the monophasic zinc hydroxycarbonate of Bhat is without any other impurity phases and whereas in contrast the basic zinc carbonate materials of the claimed invention (e.g., from Bruggemann) are composed of more than one phase (i.e., is not monophasic) and are thus multi-phasic. While this is a clever argument there are several faults with this line of reasoning. First, the instant claims are not drawn to multi-phasic basic zinc carbonate. Second, the

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identity of the impurity is unknown and could therefore be anything such as water as the Examiner has asserted above.

Applicant argues that the monophasic basic zinc carbonate of Cater and Elementis do not have the same relative zinc lability as the mutli-phasic basic zinc carbonate of Bruggemann and directed the Examiner to Table 3 of the Declaration. However, the difference in zinc lability of Bruggemann (56.9%) and Elementis (51.6%) is merely a difference in degree and not a difference in kind. In other words, they are essentially equivalent. The Declaration under 37 CFR 1.132 filed 5/25/10 is insufficient to overcome the rejection of claims 1-3, 8, 11, 12, 14, 15, and 17-28 based upon 35 U.S.C. 103(a) as being unpatentable over Bhat et al. (WO 96/25913) in view of Gavin et al. (WO 01/00151) as set forth in the last Office action because: no unexpected results have been shown as discussed above. The crystallite size of the Bruggemann sample (103 Angstroms) is only slightly less than the crystallite size of the Elementis sample (134 Angstroms) and both possess nearly the same relative zinc lability (56.9% and 51.6%) respectively. Since this is supposed to be a comparison of a 'multi-phasic' versus 'mono-phasic' samples then the Examiner can only conclude that there is no significant difference between these two samples as multi- or mono-phasic does not appear to make any difference in the resulting relative zinc lability. Also note for future reference, that scanned documents are in black and white and therefore any references to color are pointless such as in Table 2 of the Declaration. Indeed, the scans in Table 2 are virtually superimposable and given the data in Table 3 it appears that the crystallite size is more important than the phase of the material with respect to the relative zinc

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lability. However, very small particles have a higher solubility than larger particles of the same substance due to their greater specific surface area and higher surface free energy and so even this appears to be an expected result.

Respectfully, the claims remain rejected.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Primary Examiner, Art Unit 1616